



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0193; FRL-9951-57]

Tolfenpyrad; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of tolfenpyrad in or on vegetable, fruiting, group 8-10. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on agricultural commodities in the group "vegetable, fruiting, group 8-10." This regulation establishes a maximum permissible level for residues of tolfenpyrad in or on these commodities.

The time-limited tolerances expire on December 31, 2019.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0193, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution

Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.ecfr.gov/cgi-bin/text->

idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select “Test Methods and Guidelines.”

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0193 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0193, by one of the following methods:

- *Federal eRulemaking Portal: <http://www.regulations.gov>*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.*

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for residues of tolfenpyrad, 4-chloro-3-ethyl-1-methyl-N-[4-(*p*-tolylloxy)benzyl]pyrazole-5-carboxamide, in or on agricultural commodities in the group “vegetable, fruiting, group 8-10” at 0.70 parts per million (ppm). These time-limited tolerances expire on December 31, 2019.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.”

This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Tolfenpyrad on Vegetable, Fruiting, Group 8-10

Commodities and FFDCA Tolerances

The Florida Department of Agriculture and Consumer Services (FDACS) requested an emergency exemption for the use of tolfe n pyrad on fruiting vegetables to reduce damage incurred by thrips. Thrips have become a severe problem in Florida on account of their developing resistance to the insecticides currently registered for use on fruiting vegetable crops, combined with the appearance of Tomato Chlorotic Spot Virus, a newly established invasive virus disease vectored by thrips attacking fruiting vegetables. According to FDACS, substantial economic damage is occurring and 30% to 90% yield loss has been documented due to the insufficient efficacy of registered alternatives.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of tolfenpyrad on vegetable, fruiting, group 8-10 for control of thrips in Florida.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of tolfenpyrad in or on vegetable, fruiting, group 8-10. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent, non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2019, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on vegetable, fruiting, group 8-10 after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether tolfenpyrad meets FIFRA's registration requirements for use on vegetable, fruiting, group 8-10 or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of tolfenpyrad by a State for special

local needs under FIFRA section 24(c), nor does this tolerance by itself serve as the authority for persons in any State other than Florida to use this pesticide on the applicable crops under FIFRA section 18, absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for tolfenpyrad, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT.**

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of, and to make a determination on, aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerances for residues of tolfenpyrad on vegetable, fruiting, group 8-10 at 0.70 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

A. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological profile and endpoints for tolfenpyrad used for human health risk assessment is discussed in Table 1 of the final rule published in the **Federal Register** of January 9, 2014, (79 FR 1599) (FRL-9904-70).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tolfenpyrad, EPA considered exposure under the time-limited tolerances established by this action as well as all existing tolfenpyrad tolerances in 40 CFR 180.675. EPA assessed dietary exposures from tolfenpyrad in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessment are performed for a food-use pesticide if a toxicological study has indicated the possibility of an

effect of concern occurring as a result of a 1-day or single exposure; such effects were identified for tolfeprad. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). For purposes of this acute exposure assessment, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption information from the USDA 2003-2008 NHANES/WWEIA. For purposes of this chronic exposure assessment, EPA relied upon average residue levels from crop field trials. EPA also used PCT estimates (discussed further in Unit IV.B.1.iv., below) for certain commodities that were shown to have a high contribution to the overall dietary exposure, while assuming 100 PCT for the rest of the commodities.

iii. *Cancer.* Based on the data summarized in Unit IV.A., EPA has concluded that tolfeprad does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

In this case, EPA used data from the USDA NASS Agricultural Chemical Usage - Fruit Summary (2003, 2005, 2007, 2009), Vegetable Summary (2004, 2006, 2010), along with proprietary data to estimate PCT for four commodities (all others being assumed to be 100 PCT). Based on that data, EPA estimated average PCTs of 40% for oranges, 60% for apples, 65% for table grapes, and 50% for spinach.

The Agency believes that the three conditions discussed in Unit IV.B1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which tolfeprad may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for tolfeprad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tolfeprad. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of tolfenpyrad for acute exposures are estimated to be 26.9 parts per billion (ppb) for surface water and 11 ppb for ground water. For chronic exposures for non-cancer assessments, the EDWCs are estimated to be 12.2 ppb for surface water and 11 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 26.9 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration value of 12.2 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Tolfenpyrad is not registered for any specific use patterns that would result in residential exposure.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at:

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found tolfenpyrad to share a common mechanism of toxicity with any other substances, and tolfenpyrad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tolfenpyrad does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased quantitative or qualitative susceptibility was observed in developmental toxicity studies in rats or rabbits or a reproduction toxicity study in rats. However, the developmental immunotoxicity study (DIT) in rats suggests increased qualitative susceptibility in the young, since toxicity observed in offspring animals was more pronounced than toxicity seen in maternal animals at the same dose. No evidence of quantitative susceptibility was seen in the study. There is low concern and there are no residual uncertainties regarding the increased qualitative prenatal and/or postnatal susceptibility observed for tolfenpyrad. When the DIT and the reproduction study are

considered together, the offspring toxicity in the DIT is comparable in severity to maternal toxicity observed at the same dose in the reproduction study. Since the adverse effects in young occurred at exposure levels that have shown comparable effects in adults, EPA does not consider the DIT persuasive evidence of an increased susceptibility of infants or children to tolfenpyrad. Additionally, the effects observed in the DIT study are well-characterized, a clear NOAEL was identified, and the endpoints chosen for risk assessment are protective of potential offspring effects, since a dermal hazard was not identified for tolfenpyrad, inhalation risk assessments are based on a route specific inhalation study, and the POD used for chronic dietary risk assessment is lower than where offspring effects were seen in the DIT study.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for tolfenpyrad is complete.
- ii. There is no indication that tolfenpyrad is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. Although there is possibly increased qualitative susceptibility in the young in the DIT study in rats, there are no residual uncertainties regarding increased susceptibility for tolfenpyrad since, (1) comparable maternal toxicity was observed at the same dose in the reproduction study, (2) the offspring effects observed in the DIT study are well characterized and there is a clear NOAEL for the effects seen, (3) no evidence of quantitative susceptibility was seen in the DIT study and susceptibility was not observed (quantitative or qualitative) in rat or rabbit developmental toxicity or reproduction studies tested at similar doses, (4) the endpoints and PODs selected for risk assessment are protective, and (5) direct non-dietary exposure to

children is not anticipated since there are no residential uses for tolfenpyrad. Thus, a 10X FQPA safety factor is not necessary to protect infants and children.

iv. There are no residual uncertainties identified in the exposure databases.

EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tolfenpyrad in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by tolfenpyrad.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water and relevant residential exposure scenarios. Since acute residential exposure is not anticipated, acute aggregate risk from exposure to tolfenpyrad results from exposure to residues in food and drinking water alone. Therefore, acute aggregate risk estimates are equivalent to the acute dietary risk estimates. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tolfenpyrad will occupy 56% of the aPAD for the U.S. general population. Children 3-5 years old are the highest-exposed population subgroup with an estimated exposure of 81% of the aPAD. Typically, EPA has concerns when estimated

exposures exceed 100% of the acute or chronic population-adjusted dose (aPAD or cPAD). Acute dietary risk estimates are below EPA's level of concern for all populations.

2. *Chronic risk.* A chronic aggregate risk assessment takes into account chronic exposure estimates from dietary consumption of food and drinking water and relevant residential exposure scenarios. Since chronic residential exposure is not anticipated for tolfenpyrad, chronic aggregate risk from exposure to tolfenpyrad results from exposure to residues in food and drinking water alone. Therefore, chronic aggregate risk estimates are equivalent to the chronic dietary risk estimates. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tolfenpyrad from food and water will utilize 69% of the cPAD for (children 1-2 years old) the population group receiving the greatest exposure. There are no residential uses for tolfenpyrad.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background (average) exposure level). A short-term adverse effect was identified; however, tolfenpyrad is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for tolfenpyrad.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, tolfenpyrad is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for tolfenpyrad.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, tolfenpyrad is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to tolfenpyrad residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (liquid chromatography/tandem mass spectrometry (LC/MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and

agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for tolfenpyrad residues in/on fruiting vegetables.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of tolfenpyrad, (4-chloro-3-ethyl-1-methyl-*N*-[4-(*p*-tolylloxy)benzyl]pyrazole-5-carboxamide, in or on the agricultural commodity “vegetable, fruiting, group 8-10” at 0.70 ppm. This tolerance expires on December 31, 2019.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501

et seq., nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 26, 2016.

Michael L. Goodis,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.675, revise paragraph (b) to read as follows:

§ 180.675 Tolfenpyrad; tolerances for residues.

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(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of tolfenpyrad, (4-chloro-3-ethyl-1-methyl-*N*-[4-(*p*-tolylxy)benzyl]pyrazole-5-carboxamide, including its metabolites and degradates, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified below is to be determined by measuring only tolfenpyrad, 4-chloro-3-ethyl-1-methyl-*N*-[4-(*p*-tolylxy)benzyl]pyrazole-5-carboxamide. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Vegetable, fruiting, group 8-10	0.70	12/31/2019

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